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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,178	07/08/2003	Dennis M. Brown	A-71462/RFT/THR (468899-3	1122

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EXAMINER	
DESAI, RITA J	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,178	BROWN, DENNIS M.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-7 and 15-28* is/are pending in the application.

4a) Of the above claim(s) *5-7 and 15-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/25/06*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *6/9/06*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims pending 3-7,15-28.

Claims 1,2 , 8-14 have been cancelled and new claims 23-28 have been added.

Claims 5-7,22 have been amended. Claims 24-28 are new claims drawn to naphthalimide with two amine groups.

New Restriction;-

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3, 4 drawn to a process of making a amonafide compound from mitonafide using ammonium formate, classified in class 546 , subclass 98.

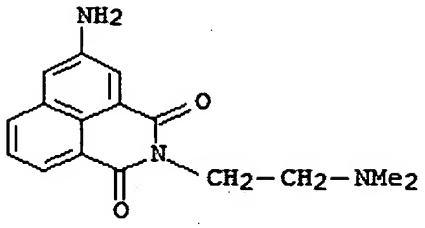
II. Claims 5-7, 15-22, 24-28, drawn to a method of making a naphthalimide comprising 2 amine group, classified in class 546, subclass 98.

III Claim 23 further converting amonafide to a salt.

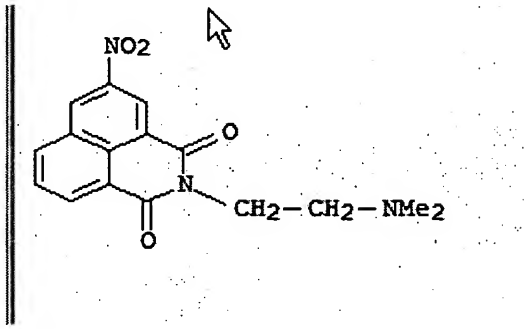
The inventions are distinct, each from the other because of the following reasons:

Inventions I and II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions, invention I is drawn to a method of synthesizing an amonafide from a mitonafide comprising a nitro group.

Amonafide has the structure

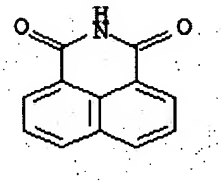


Mitonafide has the structure

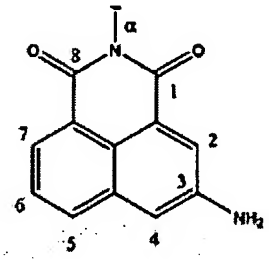


thus the process is drawn to the reduction of the NO2 group to a amine group.

Invention II is now as amended is drawn to a naphthalimide comprising 2 amine groups.

Naphthalimide is  and it comprises 2 amino groups and further protonating them using an inorganic or an organic acid.

First of all it is unclear how naphthalimide can have 2 amino groups . If it did it would be another compound. Secondly the process is drawn to forming a protonated amino group and not to the reduction of a nitro group.

But according to applicants own definition of the naphthalimide in figure 3 of the specifications it is  thus it does have a amine group.

However the invention is drawn to converting 2 amine groups to a protonated form. Thus the reagents , reactants and steps are all different and hence are drawn to two different synthesis or processes.

Invention III is drawn to the formation of a salt of amonafide . Amonafide is a known compound and applicants own specification page 1 US 5420137 teaches the preparation of the various salts.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Bernhardt on 6/ 5/06 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

It should be noted that applicants own admission on page 2 clearly indicates the different inventions.

The previously examined claims were 3 and 4 , previously presented and in the originally filed were examined and are still under examination.

In the previous office action examiner had examined the claims 3 and 4 and incorrectly found it to be allowable over the prior art.

There are New Grounds of Rejections

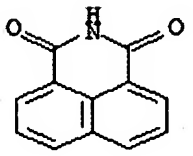
Claim Rejections - 35 USC § 112

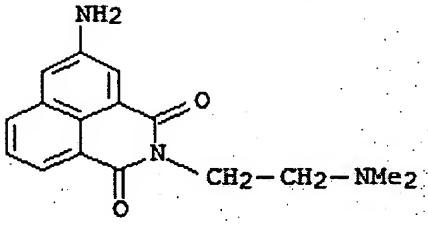
The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants specifications are interchanging using amonafide and naphthalimide.

Naphthalimide is given by the structure  and amonafide is



There is no description of what the amonafide analogs would encompass.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3,4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Applicant's claims are drawn to "amonafide analog from the mitonafide analogs" The specification defines in figure 1 the amonafide . There is no structure given to the

other analogs. The specification gives no guidance to one of ordinary skill in the art the attachment position or type of other group to form the amonafide or the mitonafide analog. The specification does not define the compound in this category. The analogs would includes a plethora of compounds, which has this core.

The expression analog with out any structure and just a mere recitation of the term does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The language recited without any correlation does not meet the written description requirement for the expression "analog " as one of ordinary skill in the art could not recognize or understand the structure from it . Claims employing language at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of compounds and applicants claimed expression represents only an invitation to experiment regarding possible compounds.

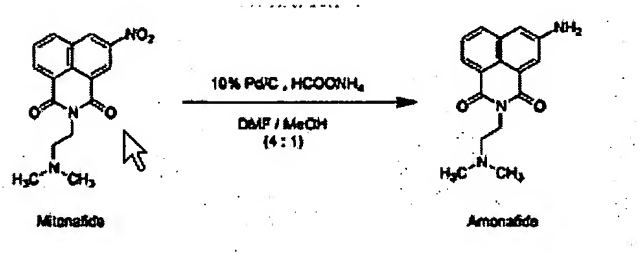
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enstwistle Ian D 1977 and Robert Johstone Heterogenous Catalytic Transfer Hydrogenation ....1985. (the references are not being sent with the office action since they have been disclosed in the specifications on page 8 of the application)

Applicants claims are drawn to a process of synthesizing amonafide from mitonafide comprising a nitro group and reducing is using a catalyst , ammonium formate and an organic solvent.



Determination of the scope and content of the prior art (MPEP §2141.01)

Enstwistle et al 1977 teaches a process of reducing an aromatic nitro group to amine using formic acid or formate salts in the presence of catalysts such as Pd. {Also see applicants own admission on page 8lines 8-10 of the specifications}

Johnstone et al 1985 teaches in scheme XXXVII which shows the mechanism of conversion of the Nitro group to the amine, using the same catalyst and an aromatic No2 group.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The prior art does not specifically show the Mitonafide to the amonafide .

However it does teach the conversion of a nitro group on an aromatic ring to an amine using the same reagents.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Thus one of skill in the art with the knowledge of converting a nitro group on an aromatic ring to an amino group would have been motivated to use the same process to convert

the nitro on a Mitonafide (which has an aromatic ring) to an amine group to synthesis the amonafide .

Conclusion

The claims 3 and 4 are not found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
June 9, 2006

R Desai 6/9/06